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Attorneys for Plaintiff Pikeville Medical Center

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PIKEVILLE MEDICAL CENTER,

Plaintiff,

v.

GENENTECH, INC.,

Defendant.

CASE NO.

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiff, Pikeville Medical Center, brings this action against Defendant, Genentech, Inc.

PARTIES

1. Plaintiff, Pikeville Medical Center is a is a Kentucky non-profit corporation.

2. Defendant Genentech is a Delaware corporation with its principal place of business in San Francisco, California. Defendant designed, developed, manufactured, tested, marketed, promoted, distributed, and sold the Product as Herceptin, an anticancer product used to treat a subset of breast cancers and certain gastric cancers. In doing so, Genentech placed the Product in the stream of commerce in California and throughout the United States. Genentech has received, and will continue to receive, substantial benefits and income through its activities. Defendant authorized the actions attributed to it herein through its officers, directors, and managing agents.

JURISDICTION AND VENUE

3. This Court has personal jurisdiction over the parties in this case. Defendant Genentech is a Delaware corporation with headquarters in this District.

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332, as there is complete diversity between Plaintiff and Defendant, and the amount in controversy exceeds \$75,000, exclusive of interest and costs.

5. Venue is proper in this District under 28 U.S.C. § 1391(a) because Defendant maintains its headquarters within this District, a substantial part of the events or misrepresentations giving rise to the claim occurred within this District.

6. Defendant is subject to this Court's personal jurisdiction.

Summary of the Case

7. Plaintiff provides healthcare services including the diagnosis and treatment of cancer. Plaintiff purchased the cancer treatment drug Herceptin, which was manufactured and distributed by Genentech. Plaintiff purchased vials of Herceptin labeled as containing 440 milligrams (mg) of medicine and suffered damages as a direct result of Genentech's fraud and breaches of warranties relating to the contents of so-called 440 mg Herceptin vials.

8. At relevant times, Genentech distributed Herceptin in vials and purporting to contain at least 440 mg of lyophilized (dehydrated or "freeze-dried") medicine. To administer the medicine, the Herceptin product was mixed, pursuant to Genentech's directions, with a liquid (diluent), also provided to end users by Genentech. Genentech claimed that, after mixing

1 the lyophilized medicine and the diluent, the resulting fluid contained 440 mg of Herceptin at a
2 concentration of 21 mg/mL.

3 9. 440 mg concentrated at 21 mg/mL would yield 20.952 mL of fluid solution.

4 10. Plaintiff discovered that after mixing the lyophilized medicine with the diluent,
5 the actual volume yielded for use by Plaintiff in treating their patients was never more than
6 20.2 mL.

7 11. Through discovery conducted in this MDL, Plaintiff learned Genentech put less
8 than 440 mg trastuzumab in the vast majority of vials sold in the United States since 2008.

9 12. Genentech shipped vials to healthcare providers so long as its testing showed the
10 vials met a manufacturing specification requiring vials to contain somewhere between 405-475
11 mg of trastuzumab.

12 13. With every vial shipped, Genentech included a prescribing information packet
13 that promised “[e]ach multi-use vial of Herceptin contains 440 mg trastuzumab,” and in other
14 communications Genentech explicitly and repeatedly reassured healthcare providers that each
15 and every multi-dose Herceptin vial actually contained at least 440 mg trastuzumab, even
16 though Genentech knew the vast majority of them did not.

17 **FACTUAL BACKGROUND**

18 ***A. Product History and Use***

19 14. Herceptin was approved in 1998 by the Food and Drug Administration (FDA)
20 for the treatment of metastatic breast cancer. Herceptin is the Genentech trade name for
21 trastuzumab, a monoclonal antibody that binds to and inactivates the Human Epidermal
22 Growth Factor Receptor-2 (HER2) on the walls of the cancer cells, thus preventing the
23 proliferation of those cells. HER2 receptors are over-expressed in certain cancers, mainly a
24 subset of breast cancers and some gastric cancers (HER-2 positive cancers). The increased
25 number of HER2 receptors in those cancers leads to faster growth and metastasis of the cancer.
26 By binding and inactivating the HER2 receptors, Herceptin slows the growth of the cancer and
27 leads to longer survival rates in late-stage (metastatic) HER2-positive cancer patients.
28

15. Herceptin was initially approved strictly for treatment of metastatic breast cancer, but its use as adjuvant therapy (treatment in conjunction with other cancer drugs) has since expanded to treat early stage HER-2 positive breast cancers and as a treatment after surgery for reducing the risk of recurrence of the disease. Herceptin is also approved for the treatment of HER2-positive metastatic cancer of the stomach or gastroesophageal junction, in combination with chemotherapy.

16. Herceptin has been the only approved effective anticancer therapy on the market for the treatment of HER2-positive tumors and is therefore the dominant breast cancer drug on the market.

17. Herceptin is extremely expensive. It costs about \$70,000 for a course of treatment, which normally consists of a full year of weekly infusions (52 treatments). Since its purchase of Genentech, Roche has been steadily building the sales of this drug around the world. The world-wide Herceptin sale was estimated to be near \$5 billion in 2011, and over \$6 billion in 2012.

18. In 2014, Genentech announced that it no longer distributed Herceptin through the general line wholesalers. Instead, it has since marketed Herceptin, along with two other blockbuster cancer drugs, through its specialty distributors. This practice has deprived hospitals and oncology clinics from standard industry discounts routinely offered by general wholesalers, with Genentech and its distributors further profiting from the price difference.¹

B. Preparation and Administration of Herceptin

19. Up until 2017, Herceptin was marketed in multi-dose vials, with each vial labeled and warranted by Genentech as containing 440 milligrams (mg) of the drug.²

20. Herceptin is a biological molecule and can therefore easily break down and lose its potency, especially when dissolved as a solution. For this reason, it is marketed as a

¹ See <http://time.com/3541484/cancer-drug-price-hikes/>.

² In 2015, Genentech decided to discontinue the production and distribution of “440 mg” vials of Herceptin. This lawsuit relates to only those vials labeled and sold as “440 mg” vials of Herceptin.

“lyophilized” powder³ which is to be dissolved in a liquid (“diluent,” normally sterile water containing benzyl alcohol) also provided by Genentech, prior to administration of the drug. The mixing process is accomplished by injecting the provided liquid into the vial containing the lyophilized Herceptin.

21. The process of adding the provided liquid to the vial containing Herceptin powder is known as reconstruction. By reconstituting Herceptin based on the instructions provided by Genentech, a multi-dose solution is obtained.

22. Herceptin vials are labeled as containing 440 mg of the drug. Genentech Prescription Information represents that its reconstituted multi-dose Herceptin solution contains 21 mg of Herceptin per each milliliter of the solution (21 mg/mL).

23. Herceptin Prescription Information instructed the healthcare providers to: “Reconstitute each 440 mg vial of Herceptin with 20 mL [milliliters]⁴ of Bacteriostatic Water for Injection (BWHI), USP, containing 1.1% benzyl alcohol as a preservative to yield a multi-dose solution containing 21 mg/mL trastuzumab.” *Id.* at 4.

24. Depending on the purpose of the treatment, patients are to be given a dose of 2 to 8 mg Herceptin/Kg weight. For a person weighing about 150 lbs., that translates to an amount of Herceptin ranging from 136 mg to 544 mg.

25. Under the Heading of “**Dilution**,” Genentech instructed the providers to:

Determine the dose (mg) of Herceptin [see Dosage and Administration (2.1)]. Calculate the volume of the 21 mg/mL reconstituted Herceptin solution needed, withdraw this amount from the vial and add it to an infusion bag containing 250 mL of 0.9% Sodium Chloride Injection, USP.

Id.

26. When administering the required Herceptin dose to each patient, Plaintiff prepared and administered Herceptin as instructed by Genentech, and in doing so relied upon

³ The process of lyophilization (freeze-drying) allows a substance to be isolated from a solution under vacuum while being kept at low temperatures. This process is used to extract substances which would decompose upon heating.

⁴ One fluid ounce contains roughly 30 mL.

Genentech's express representation that the concentration of the reconstituted solution is 21 mg/mL.

27. In administering the Herceptin from the multi-dose vials, Plaintiff withdrew the amount of reconstituted Herceptin necessary for each patient until each vial is emptied.

28. Relying on Genentech's representation that the reconstituted Herceptin solution has a concentration of 21mg/mL, Plaintiff provided sufficient volume of the solution to administer the required amount of Herceptin.

29. For instance, to treat a patient weighing 150 lbs. with a 2 mg/Kg dose of Herceptin for a weekly treatment, 6.5 mL of the reconstituted Herceptin solution would be required.⁵

30. Per the Prescription Information instructions, after reconstitution, the Herceptin solution should be used within 28 days and any unused Herceptin must be discarded after 28 days. For those patients who are allergic to benzyl alcohol, Herceptin is to be reconstituted with sterile water, and such solution is to be discarded immediately after use. *Id.*

B. Production of Trastuzumab

31. Trastuzumab, a biological product, is produced by a specialized Chinese hamster ovary cell line. The produced trastuzumab ("drug substance") is harvested, quantified, and brought to a protein concentration approved by the FDA of 25±1mg/mL. *In re: MDL 2700 Genentech Herceptin (Trastuzumab) Marketing and Sales Practice Litigation*, 960 F.3d 1210, 2016 (10th Cir. 2020), attached hereto as **Exhibit 1**.

32. The drug substance is then filtered, sterilized, and dispensed into glass vials by automated filling machines with a target fill weight for each multi-dose vial is 17.92 grams. Per the biologics license application ("BLA") filed by Genentech and approved by the FDA the filled vials must have a fill weight range of 17.74 to 18.10 grams. *Id.* at 1216.

33. The trastuzumab solution in the vials is lyophilized and the vial containing solid drug substance is sealed. *Id.* Because of the variation in the concentration of the trastuzumab in

⁵ 150 lbs. = 68 Kg x 2 mg Herceptin/Kg=136 mg Herceptin÷21 mg Herceptin/mL= 6.5 mL

1 the drug substance, the BLA allowed for a range of protein amount around 440 mg, *i.e.*,
2 440±35, or a range of 405 to 475 mg in each vial. *Id.* In the absence of intentional manipulation
3 of the production process, a random distribution of vial contents below and above 440 mg is
4 expected.

5 **C. Misrepresentations by Genentech**

6 34. The BLA submitted by Genentech to the FDA stated the amount of trastuzumab
7 per mL to be 25.0 mg and the nominal amount of trastuzumab in each vial to be 440 mg. *Id.* at
8 1217. The BLA stated that the Herceptin vials were configured to deliver 440 mg trastuzumab
9 per vial. *Id.* “[T]he FDA-approved Prescribing Information for Herceptin stated that Herceptin
10 is supplied in a multi-use vial containing 440 mg trastuzumab as a lyophilized sterile powder,
11 under vacuum.” *Id.*

12 35. Until 2017, cartons of multi-dose vials of Herceptin shipped to healthcare
13 providers stated on the front: “Herceptin© trastuzumab 440 mg.” *Id.* at 1218.

14 36. Between 1998 and 2017, Genentech included a prescribing information packet
15 that stated: “Each multi-use vial of Herceptin contains 440 mg trastuzumab” with every vial
16 shipped. *Id.*

17 37. However, Genentech manipulated the minimum fill weight of the Herceptin
18 vials to routinely deliver less than 440 mg of trastuzumab in each vial.

19 38. The average fill weight of Herceptin vials, as well as the concentration of the
20 drug substance were routinely lower than the range required per the BLA.

21 39. While in the absence of any process manipulation, statistically a range of
22 weights around the mean of 440 mg both *above and below* the stated 440 mg of trastuzumab
23 would be expected, most Herceptin vials contained less than 440 mg.

24 40. Genentech had considerable control over its manufacturing processes and the
25 amount of trastuzumab per vial. *Id.* at 1219. However, between 1998 and 2017, the average
26 amount of trastuzumab per vial dropped by 15 mg. *Id.* The downward trend of the average
27 amount of trastuzumab per vial was the result of knowing and intentional acts by Genentech.
28 *Id.* at 1238-89.

41. Since 2009, the majority of the Herceptin vials sold contained less than 440 mg trastuzumab. *Id.*

42. Despite its knowledge of manufacturing and delivering vials containing less than 440 mg trastuzumab, Genentech for years represented that each and every vial labeled as 440 mg actually contained at least 440 mg trastuzumab, and repeatedly and consistently reassured healthcare providers of that purported fact.

43. In response to inquiries by healthcare providers regarding the discrepancy between the nominal 440 mg amount stated on the label of Herceptin vials vs. the amount providers calculated that they could actually extract from each vial, Genentech reassured them that the vials contained a *minimum* of 440 mg. *Id.* at 1219.

FIRST CAUSE OF ACTION

Fraud

44. Plaintiff adopts and incorporates all of the preceding allegations and further alleges as follows.

45. Genentech made false representations to healthcare providers, including Plaintiff, regarding 440 mg Herceptin vials, as alleged above, including false representations that each and every 440 mg vial of Herceptin contained at least 440 mg trastuzumab.

46. Genentech knew the false representations were indeed false when Genentech made them.

47. Genentech made such false representations with the intent to defraud healthcare providers, including Plaintiff, who purchased 440 mg Herceptin vials.

48. Healthcare providers, including Plaintiff, relied on Genentech's false representations in purchasing, administering, and billing for the use of 440 mg Herceptin vials.

49. Genentech also failed to disclose, and concealed, facts material to the decisions of healthcare providers, including Plaintiff, regarding their purchase, administration, and billing for the use of 440 mg Herceptin vials.

50. Healthcare providers, including Plaintiff, suffered financial damage as a direct result of Genentech's fraudulent conduct.

SECOND CAUSE OF ACTION

Breach of Express Warranty

51. Plaintiff adopts and incorporates all of the preceding allegations and further allege as follows.

52. Genentech has marketed Herceptin through general and specialty distributors.

53. Beginning in 1998, Plaintiff relied on all representations and warranties made by Genentech concerning the quantity of Herceptin purchased from Genentech.

54. Beginning in 1998, Plaintiff relied on all representations and warranties made by Genentech concerning the concentration of the fluid solution of reconstituted Herceptin purchased from Genentech.

55. In Plaintiff's experience, reconstituting each vial of Herceptin yields no more than 20.2 mL rather than the 20.952 mL that follows mathematically from Genentech's representations and warranties.

56. Genentech's representations and warranties were material to Plaintiff and were material to its purchase and use of Herceptin.

57. Genentech's false representations and warranties relied upon by Plaintiff include that each vial purchased by Plaintiff contained at least 440 mg of trastuzumab.

58. Genentech has made express warranties regarding the quantity of trastuzumab in each sold vial (440 mg), and the concentration of reconstituted Herceptin (21 mg/mL).

59. If Genentech had ensured each vial contained at least 440 mg of trastuzumab, each reconstituted vial of Herceptin would yield fluid solution with a concentration of 22 mg/mL. In that case, Genentech's representation and warranty that each reconstituted vial of Herceptin yielded fluid solution with a concentration of 21 mg/mL would have been breached.

60. Genentech knew or should have known that its representations and warranties that a vial of the Herceptin contains 440 mg of this drug, or its representation that each mL of the reconstituted Herceptin solution contains 21 mg of this drug, were untrue or misleading. Genentech made these representations and warranties with the intent to induce Plaintiff into purchasing more Herceptin than they required.

1 61. Plaintiff relied on Genentech's representations and warranties regarding the
2 quantity of Herceptin in each sold vial and the concentration of reconstituted Herceptin
3 purchased from Genentech. These representations and warranties were material in influencing
4 Plaintiff's decision regarding the quantities of the Product needed and purchased.

5 62. As a result of Genentech's breach of express warranty, Plaintiff has suffered
6 damages in fact, lost money and property, and continues to be damaged, due to the additional
7 vials of Herceptin it was and is forced to purchase.

8 **THIRD CAUSE OF ACTION**

9 **Breach of Implied Warranty**

10 63. Plaintiff adopts and incorporates all of the preceding allegations and further
11 allege as follows:

12 64. Genentech has marketed Herceptin through general and specialty distributors.

13 65. In marketing Herceptin as a merchantable product, Genentech was required to
14 provide goods that would conform to the promise or affirmations of fact made on the container
15 or label of the Product.

16 66. Genentech breached its warranty of merchantability by providing Plaintiff with
17 Herceptin that did not conform to the promise and affirmation of the trastuzumab quantity
18 represented and warranted by Genentech.

19 67. Plaintiff relied on Genentech's representations and affirmations regarding the
20 quantity of trastuzumab in each sold vial and the concentration of reconstituted Herceptin
21 purchased from Genentech. These representations and affirmations were material in
22 influencing Plaintiff's decision regarding the quantities of the Product needed and purchased.

23 68. As a result of Genentech's breach of the implied warranty of merchantability,
24 Plaintiff has suffered damages in fact, lost money and property due to the additional vials of
25 Herceptin it was forced to purchase.

FOURTH CAUSE OF ACTION

Violation of the False Advertising Law

(Cal. Bus. & Prof. Code § 17500)

69. Plaintiff adopts and incorporates all of the preceding allegations and further allege as follows:

70. Genentech has engaged in false advertising within the meaning of California Business and Professions Code sections 17500, *et seq.* based on the conduct herein alleged. As a result of Genentech's conduct, Plaintiff suffered injury in fact and lost money or property.

71. Genentech's representations and actions emanate from its headquarters, which are based in this state, and were disseminated to the public in California and other states.

72. Genentech represented that one vial of the Product contains 440 mg Trastuzumab and that the reconstituted solution of Herceptin has a concentration of 21 mg/mL.

73. Genentech knew or should have known that their representations that a vial of Herceptin contains 440 mg Trastuzumab, and that the reconstituted solution of Herceptin has a concentration of 21 mg/mL, were untrue or misleading. Defendant made these representations with the intent to make unwarranted additional profit by providing less than represented Trastuzumab and to induce Plaintiff into purchasing more vials of Herceptin.

74. Plaintiff relied on Genentech's representations and non-disclosures. These representations and non-disclosures played a significant part in influencing Plaintiff's decision to purchase more Herceptin than necessary. Plaintiff suffered injury in fact and lost money and property as a result of the misconduct alleged herein.

75. Pursuant to California Business and Professions Code Section 17535, Plaintiff seeks all relief available thereunder, including equitable relief, in the form of restitution or disgorgement, by Genentech for unneeded Herceptin that Plaintiff was forced to buy because of Genentech' unlawful and unfair business practices, and/or disgorgement of all revenues, earnings, profits, Genentech's compensation and benefits which may have been obtained by Genentech as a result of such business acts or practices; and an injunction enjoining Genentech from their unlawful and unfair business activities as alleged herein.

FIFTH CAUSE OF ACTION

Violation of the Unfair Competition Law

(Cal. Bus. & Prof. Code §§ 17200 et seq.)

76. Plaintiff adopts and incorporates all of the preceding allegations and further allege as follows:

77. Genentech has engaged in unlawful, unfair, and fraudulent business acts within the meaning of California Business and Professions Code sections 17200, *et seq.* based on the conduct herein alleged. As a result of Genentech's conduct, Plaintiff suffered injury in fact and lost money or property.

78. Genentech's unlawful business practices include, but are not limited to:

- a. Misrepresenting the amount of trastuzumab in each vial sold;
- b. Misrepresenting the concentration of the reconstituted Herceptin.

79. Genentech's business practices are unlawful in that its conduct constitutes a violation of the False Advertising Law (Cal. Bus. & Prof. Code, §§ 17500 *et seq.*).

80. Genentech' unfair business practices include, but are not limited to:

- a. Misrepresenting the amount of trastuzumab in each vial sold;
- b. Misrepresenting the concentration of the reconstituted Herceptin.

81. Genentech's business practices are unfair because they bestowed an unwarranted profit to Genentech with placing less Trastuzumab than represented in the vials and because they forced Plaintiff to purchase more Herceptin than necessary. Genentech' practices are unethical, oppressive, unscrupulous and/or substantially injurious to Plaintiff. Genentech draw significant economic benefits from the sale of Herceptin and further economic benefit to Genentech cannot justify the economic loss and injury suffered by Plaintiff.

82. Genentech's unfair business practice caused Plaintiff substantial harm in the amount of thousands of dollars spent on receiving a less than warranted amount of Trastuzumab and also spent on purchasing unnecessary Herceptin. Genentech's unfair practice is not outweighed by any countervailing benefit to Plaintiff. Plaintiff could not have reasonably avoided this harm based on the false representations of Genentech.

1 83. Genentech's fraudulent business practices include, but are not limited to:

- 2 a. Misrepresenting the amount of Trastuzumab in each vial sold;
3 b. Misrepresenting the concentration of the reconstituted Herceptin.

4 84. Genentech's business acts are fraudulent because Genentech's representations
5 were likely to deceive reasonable people and did deceive Plaintiff into purchasing more
6 Herceptin than necessary.

7 85. Genentech made the representations, *supra*, while knowing that they either
8 provided less Trastuzumab than represented or that they misrepresented the concentration of
9 the reconstituted solution of Herceptin.

10 86. In reliance on Genentech's representations, Plaintiff received less trastuzumab
11 than it paid for and/or was forced to purchase more Herceptin than necessary and suffered
12 actual and monetary injury.

13 87. Plaintiff has standing to pursue this claim because it has suffered injury in fact
14 and loss of money and/or property as a result of the wrongful conduct alleged herein.
15 Genentech's business acts and practices, as alleged herein, have caused injury to Plaintiff.

16 88. Pursuant to California Business and Professions Code Section 17203, Plaintiff
17 seeks all relief available thereunder including, equitable relief, in the form of restitution or
18 disgorgement, by Genentech for the shortage of trastuzumab in Herceptin vials and for the
19 unnecessary Herceptin vials that Plaintiff was forced to purchase because of Genentech's
20 unlawful and unfair business practices, and/or disgorgement of all revenues, earnings, profits,
21 Genentech's compensation and benefits which may have been obtained by Genentech as a
22 result of such business acts or practices, and an injunction enjoining Genentech from their
23 unlawful and unfair business activities as alleged herein.

24 **SIXTH CAUSE OF ACTION**

25 **Unjust Enrichment**

26 89. Plaintiff adopts and incorporates all of the preceding allegations and further
27 allege as follows:
28

1 90. Genentech's misrepresentation of the amount of trastuzumab in each sold vial,
2 and/or of the concentration of the Herceptin reconstituted solution, has cheated Plaintiff of the
3 Herceptin it paid for and/or forced Plaintiff to purchase extra, unnecessary Herceptin vials.

4 91. Placing less than represented trastuzumab in the sold vials and purchase of the
5 extra, unnecessary vials of Herceptin by Plaintiff conferred a benefit upon Genentech.

6 92. Genentech has received an unfair benefit through its practice of
7 misrepresentation as set forth *supra*.

8 93. Due to Genentech's misrepresentations, Plaintiff has suffered economic
9 damages while Genentech has enjoyed unjust enrichment.

10 94. Under the circumstances, as alleged herein, the retention of that benefit is
11 inequitable and would unjustly enrich Genentech, to the detriment of Plaintiff.

12 **Fraudulent Misrepresentation/Concealment and Tolling of the Statute of Limitation**

13
14 95. As set forth *supra*, Genentech concealed Plaintiff's potential claims through
15 fraudulent misrepresentations and material omissions.

16 96. Genentech made fraudulent misrepresentations and material omissions that
17 concealed material facts regarding the amount of trastuzumab in Herceptin vials.

18 97. Genentech assured healthcare providers, including Plaintiff, that the multi-dose
19 Herceptin vials contained a minimum of 440 mg trastuzumab despite the fact that it *was aware*
20 that the sold Herceptin vials contained less than the stated amount of 440 mg.

21 98. Genentech had a duty to disclose the true and accurate amount of trastuzumab in
22 each Herceptin vial.

23 99. Genentech breached its duty to disclose the true and accurate amount of
24 Herceptin.

25 100. Genentech's fraudulent misrepresentations and material omissions estop, toll,
26 and/or prevent the running of the statute of limitations on all Plaintiff's claims.

27 **REQUEST FOR RELIEF**

28 WHEREFORE, Plaintiff respectfully prays for judgment against Genentech, including:

1. Compensatory damages suffered by Plaintiff in an amount to be determined at trial;
2. Punitive or exemplary damages as allowed by law;
3. Prejudgment and post-judgment interest on all damages as allowed by law;
4. Costs of suit;
5. Attorneys' fees; and
6. All other just and proper relief.

DEMAND FOR A JURY TRIAL

Plaintiff demands a jury trial on all claims so triable to a jury.

Respectfully Submitted,

DATED: February 18, 2022

By: /s/ Elise Sanguinetti

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